

An Open Source Clinical Quality Measure Testing and Certification Tool



Health in the 21st Century





Goals

- Proposed to be the rigorous and repeatable testing tool of Electronic Health Records (EHRs) and EHR modules in calculating Meaningful Use (MU) Stage 2 Clinical Quality Measures (CQMs)
- CQM certification criteria addressed by Cypress include:
 - Capture and Export the capability of EHR technology to create a data file that can be incorporated by another EHR technology which could be used to calculate CQMs
 - Import and Calculate the capability of EHR technology to incorporate data (from another EHR technology where necessary) and correctly calculate the result for CQMs
 - Electronic Submission the capability of EHR technology to create a standard data file that can be electronically accepted by the Centers for Medicare and Medicaid Services (CMS)





Test Capabilities

- Cypress v2 provides 4 tests in support of CQM certification:
 - Extensible Markup Language (XML) Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category 1 standard for individual patient-level data used for CQM calculation
 - 2. XML Data conformance testing of the QRDA **Category 3** standard for aggregate reporting of CQM calculation
 - Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Provider (EP) CQMs
 - 4. Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Hospital (**EH**) CQMs





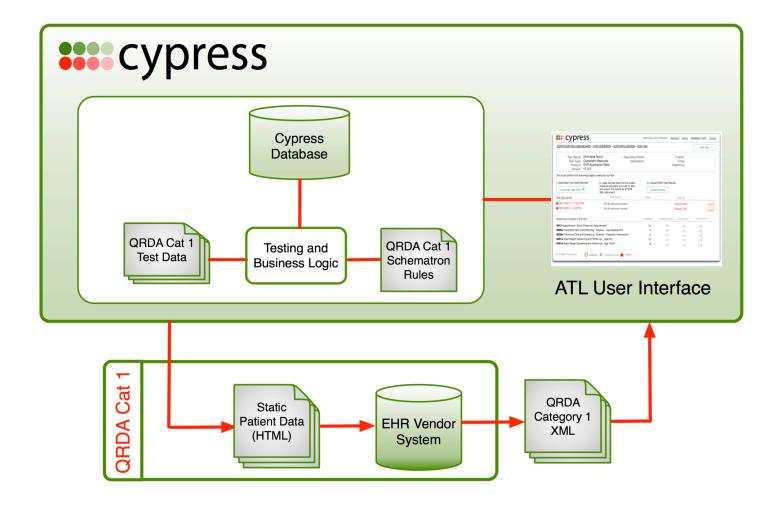
Intended Users

- Authorized Testing Labs (ATLs)
- Planned to serve as the official testing tool for the 2014 EHR Certification program supported by the Office of the National Coordinator for Health IT (ONC)
- Cypress is open source and freely available for use or adoption by the health IT community, including EHR vendors and authorized testing labs
 - Any EHR vendor may use Cypress to pre-test software packages for certification readiness
 - EHR vendors will have access to not only the Cypress service, but also the underlying source code
 - Provides transparency and accessibility to the underlying Cypress software for federal stakeholders





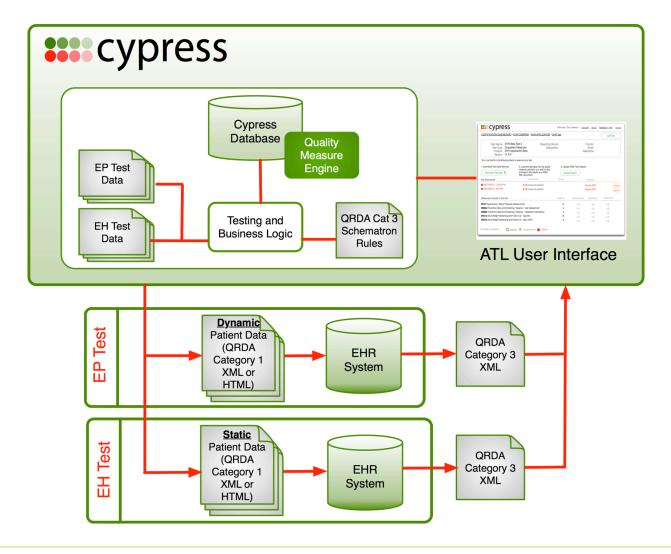
Concept of Operations Capture and Export







Concept of Operations Import, Calculate, Electronic Submission





Cypress v2 ATL Test Proctor Workflow

- Test Proctor will be the sole user to interact with Cypress v2 interface
- Test Proctor will work with EHR vendor (possibly remotely, possibly face-to-face) to identify CQMs to be tested under the various testing modes
- Test Proctor will provide all Cypress patient test inputs to EHR vendor
- Test Proctor will be responsible for overseeing the EHR vendor's capture/import/export during the test
- Test Proctor will be responsible for uploading any artifacts from the EHR into Cypress
 - QRDA Category 1 XML
 - QRDA Category 3 XML
- To Be Determined (TBD) Federal stakeholder policy decision whether the ATL Test Proctor will have the ability to "manually override" Cypress test results in the Cypress tool





What is a Passing Grade in Cypress?

- For QRDA Category 1 and Category 3 Schematron validation:
 - Any errors constitute a failure
 - Any warnings constitute a warning
 - Cypress will highlight where in the XML the Schematron errors and warnings were encountered to allow EHR vendor to fix software issue in their product
- For CQM accuracy calculation:
 - EHR vendors will have to have the exact summary CQM results in QRDA Category 3 XML
 - For example, if the CQM expected 2 patients in numerator and 5 in denominator, then any value other than 2/5 will constitute a failure
 - Cypress will be able to provide the full details of the patients that were expected for the 2 numerator results and 5 denominator results to allow an EHR vendor to either dispute the result or to fix software issue in their product



Cypress v2 Certification Test Data Overview

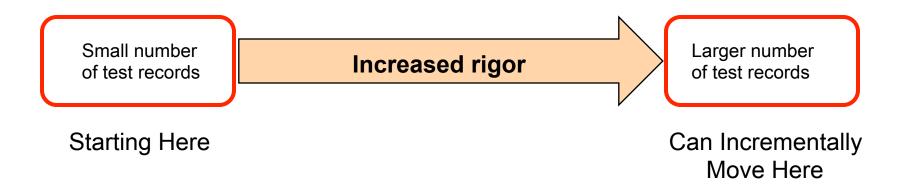
- Expected results for a set of known patients Authoritative
 - Conformance with standards and accuracy of CQM calculation
- Maximum confidence from minimum data entry
 - Minimize vendors' manual data entry burden
- 3 Cypress test decks include:
 - QRDA Category 1 Test Data for verifying conformance with the QRDA Category 1 standard
 - EP CQM Test Data for certification testing of accurate calculation of EP measures
 - EH CQM Test Data for certification testing of accurate calculation of EH measures
- Certification is a spot check of vendor performance not an exhaustive test





Cypress v2 Patient Test Data

- Level of confidence in accuracy of CQM calculations
 - Support manual entry of test records by vendors
 - Support future capability for automated import of test data
 - MITRE is working to balance EHR manual entry burden with rigor in exercising various logical paths through CQMs







Cypress v2 Patient Test Data

- How long will it take to test an EHR vendor with Cypress?
 - Currently an unknown, and will be valuable information to collect in beta pilots in early Dec 2012 with ATL and EHR vendors
- Manual Data Entry
 - Time to load patient data dependent on the number of CQMs that the EHR vendors wants to be certified for
 - Estimate to fully test all 64 of the EP CQMs and all 29 EH CQMs for both QRDA Validation and CQM Calculation Accuracy is approximately 2 days for manual data entry of the approximately 200 patient records
 - Fully automated import of Cypress patient data will radically reduce this time to a few minutes





QRDA Category 1 and 3 Validation

- MITRE is integrating testing files developed by a contractor into Cypress v2
 - Schematron XML validation rules
 - Errors cause failure
 - Warnings are notified to ATL user, but do not fail EHRs

QRDA Category 1 Validation

QRDA Category 3 Validation

Patient-level data

Aggregate-level data





EP CQM CALCULATION TEST





MU Stage 2 EP Test Deck

- Draft version of the Cypress EP Test Data consists of <u>36</u> patients
 - At least 2 DEN and 1 NUM patient for each of the 64 EP CQMs
 - Cypress is not testing all the Multi-Numerator permutations
 - Cypress is testing a portion of the Exclusion logic by including at least one path through each of the Recommended Core EP CQMs
 - Exception logic was not targeted at this time
- Range is from 1 to 34 data points per patient
- This work and the patient records are currently being vetted by MU Stage 2 measure stewards



Measure Pathway Example

Sample mapping of a pathway through the Cholesterol Screening – Risk measure logic to the Cypress Test patient data on the right

Population criteria

```
----- Population Criteria 1 ----- <High Risk>
  Initial Patient Population 1 = \langle Patients | are 20-80 \rangle years old at start of measurement
   period, plus encounter>
        o AND: "Occurrence A of Encounter, Performed: Cholesterol Measure Encounter Codes"
           during "Measurement Period"
       o AND:
                   AND: "Patient Characteristic Birthdate: birth date" >= 20 year(s) starts before
                    start of "Measurement Period"

    AND: "Patient Characteristic Birthdate: birth date" < 80 year(s) starts before start</li>

                   of "Measurement Period"
   Denominator 1 =
          AND: "Initial Patient Population 1"
          AND: <fasting LDL-C or a calculated LDL-C test>

    OR: "Laboratory Test, Performed: LDL Test" during "Measurement Period"

                   OR:

    AND: "Laboratory Test, Performed: Total Cholesterol"

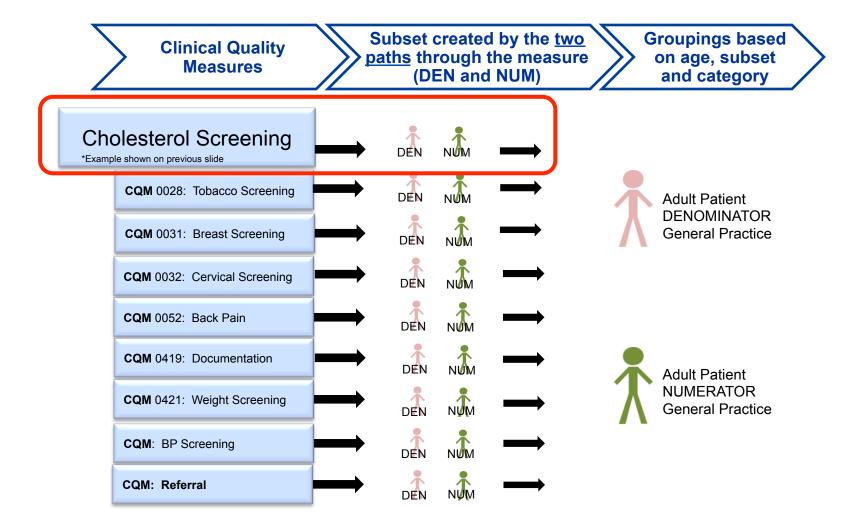
    AND: "Laboratory Test, Performed: High Density Lipoprotein (HDL)"

                           AND: "Laboratory Test, Performed: Triglycerides"
                           during "Measurement Period"
        o AND:
                   OR: "Diagnosis, Active: CHD or CHD Risk Equivalent" starts before or during
                    "Occurrence A of Encounter, Performed: Cholesterol Measure Encounter Codes"
                    <CHD or CHD Risk Equivalent>
                   OR:
```

Cypress Test Patient data will be listed in this column: Patient has a cholesterol encounter Patient is 45 years old Patient has an LDL test Patient is diagnosed with CHD



Measure Pathway Grouping Example

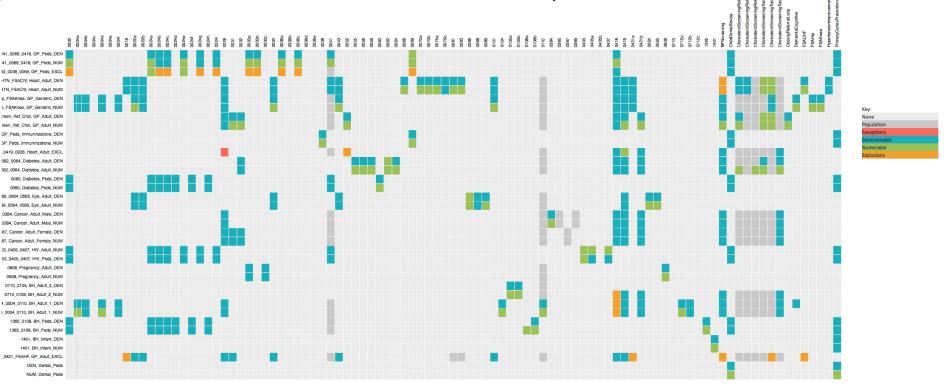


Cypress Test Data Alignment



- Below is a matrix of the Cypress MU Stage 2 EP
 Test Data applied against the MU EP CQM space
 - X-axis on the top includes all the MU CQMS

Y-axis on the left includes all the test patients

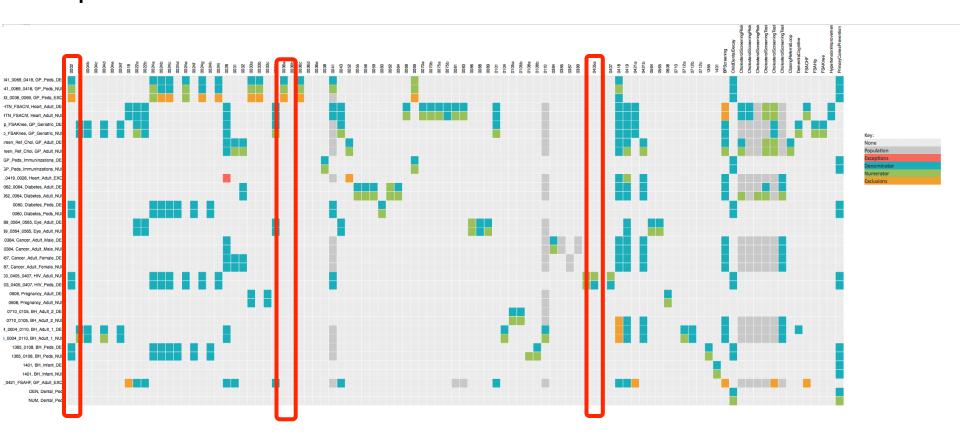




Measure Selection



 Measures selected by vendor will determine which patients to use... assume these 3 EP CQMs are selected

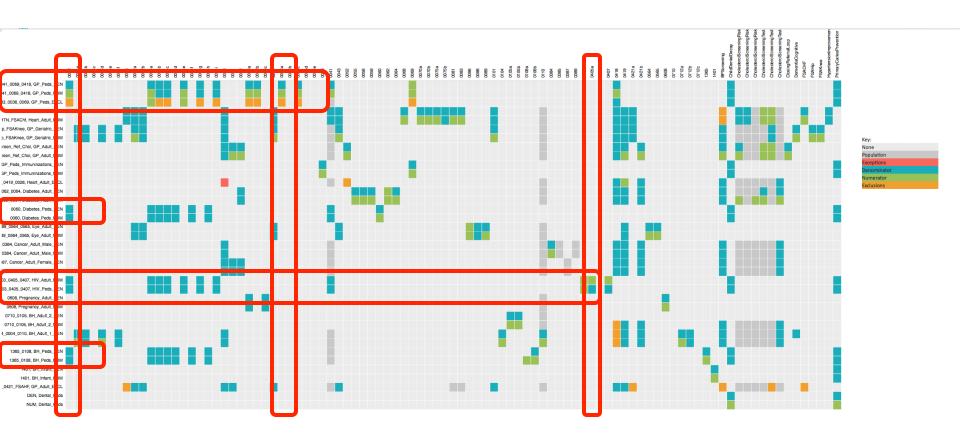




Patient Identification



 Cypress will identify 9 patients that can exercise numerator/ denominator and some exclusion for the 3 CQMs

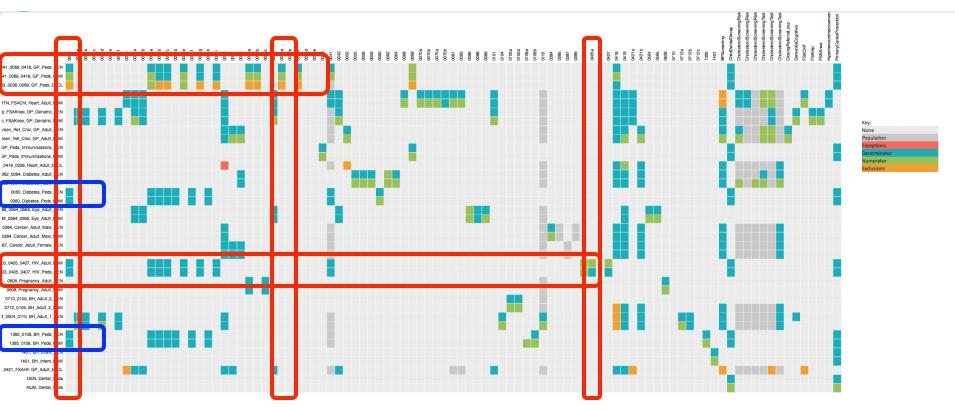




Patient Matching



 When possible, Cypress will remove additional patients if other patients can provide more coverage and still have 1 numerator and 2 denominator matches

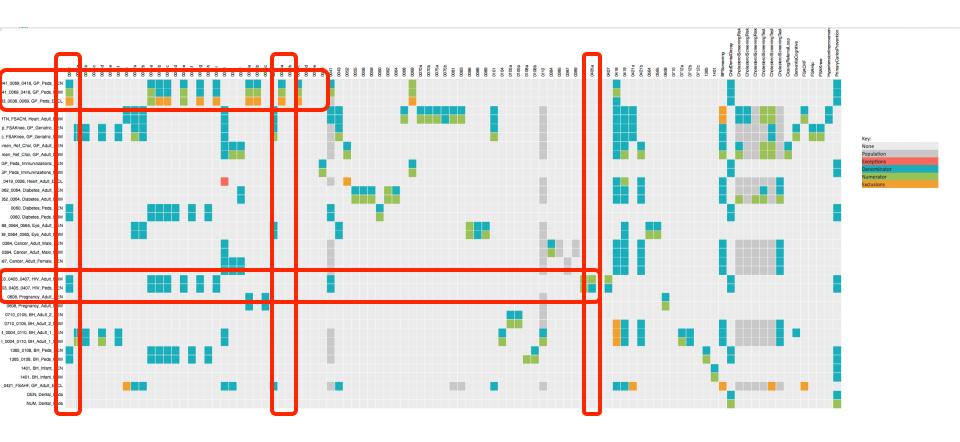




Final Test Patients



 These 5 patients can now provide a minimal test to exercise the 3 selected EP CQMs







Testing Randomization

Guarding against gamesmanship with randomization

- Cypress will introduce some variability and randomness by "cloning" a patient that meets numerator logic for each CQM
- Final randomization for EP Data will be ready for January release
 - Random removal of conditions/encounters/medications/etc. from "cloned" patient
 - Random modification of values like blood pressure (BP)/labs from "cloned" patient
- Cypress v2 Quality Measure Engine (QME) software is key to this recalculation of randomized data
 - Machine executable logical code driven from the Healthcare Quality Measure Format (HQMF) definitions of the EP CQMs on CMS site
 - Capable of recalculating expected results for any of the EP CQMs
 - Capable of calculating results for any part of the EP CQMs





EH TEST DATA





MU Stage 2 EH Test Deck

- Requires manual inspection of the 29 EH CQMs by MITRE staff and measure stewards
- Draft version of the EH Test Data currently consists of <u>20</u> <u>patients</u> covering 29 measures
 - At least 2 DEN and 1 NUM patient per measure
- MITRE is currently reviewing to verify results of test data to the EH measures as well as updating patients according to any logic changes
 - EH measures have less overlap in the populations than the EP measures
 - Result is a higher patient to measure ratio in the EH deck just to test denominator and numerator pathways
- EH CQM testing will not be dynamic/random until April 2013 because the Quality Measure Engine will not be enhanced to support non numerator/denominator CQM calculation





QRDA CATEGORY 1 TEST DATA





QRDA Category 1 Test Data

- Cypress presents a single patient record to fully exercise all clinical attributes in a CQM for generation of a single QRDA Category 1 XML document
- These patient records represent all the clinical attributes which could be used for a CQM, and are not designed to be realistic patient records





TESTING AND PILOTS





Cypress v2 Testing and Pilots

- Cypress v2 Beta Pilots
 - Require both ATL <u>and</u> EHR vendor
 - Meant to test both workflow but also maturity of Cypress software
 - Ideally, pilots start early December 2012
 - EHR vendor readiness for December and MU Stage 2 CQMs and data standards is a risk to this plan
 - ATL feedback is welcome on this plan





EP TEST SCREENSHOTS

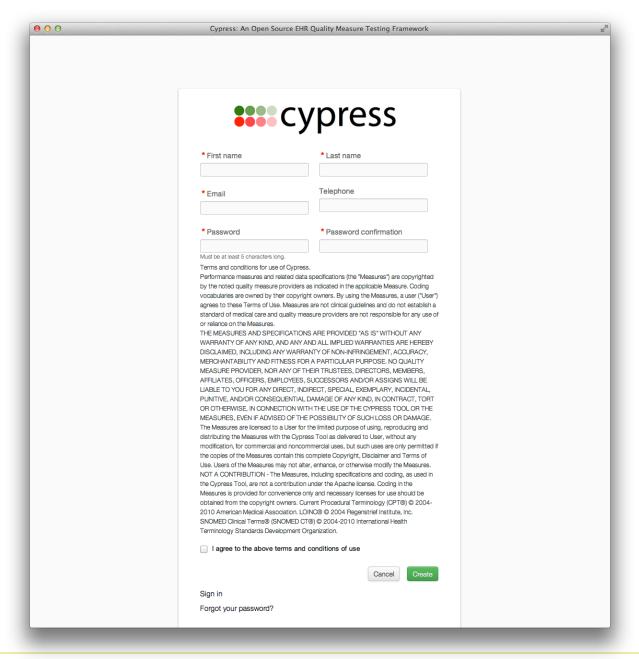












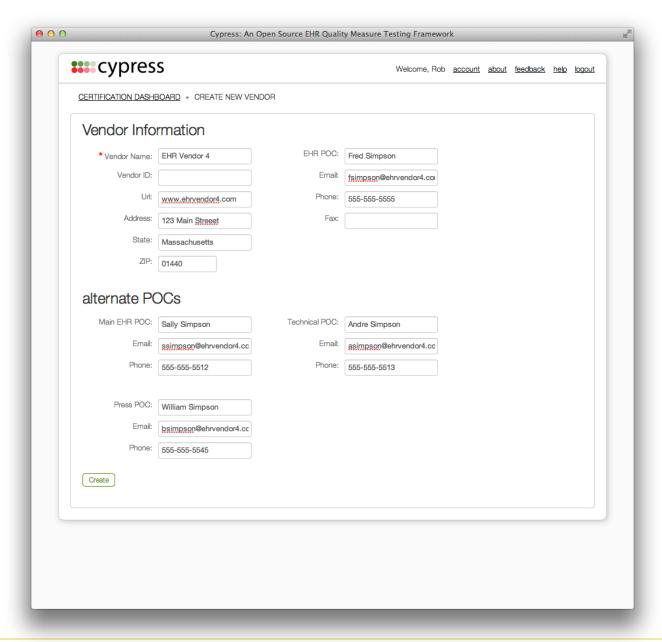






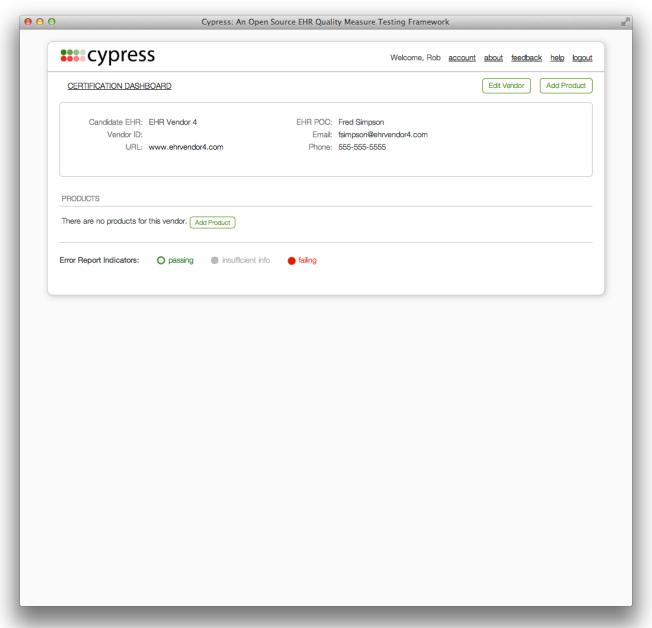






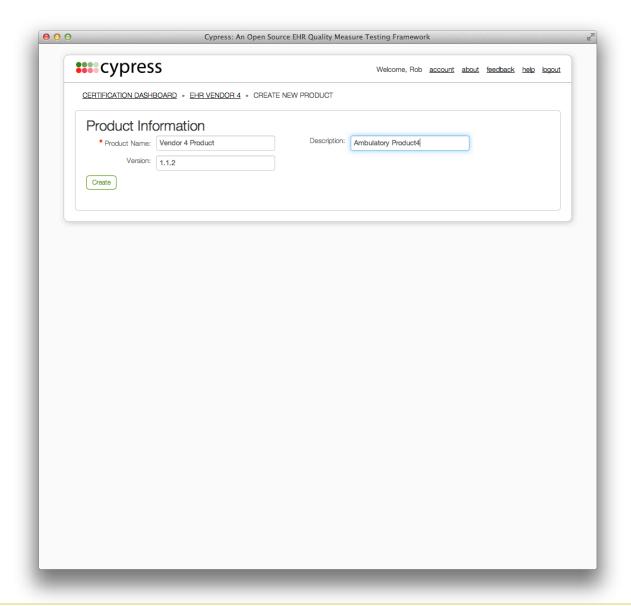






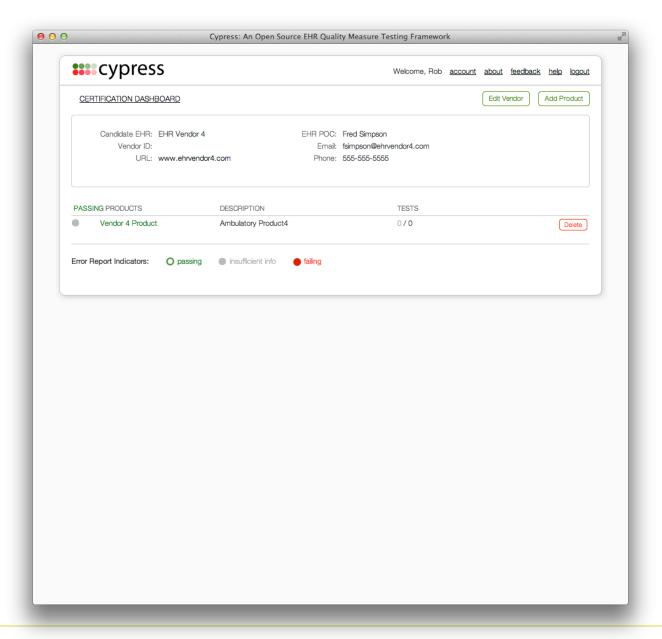






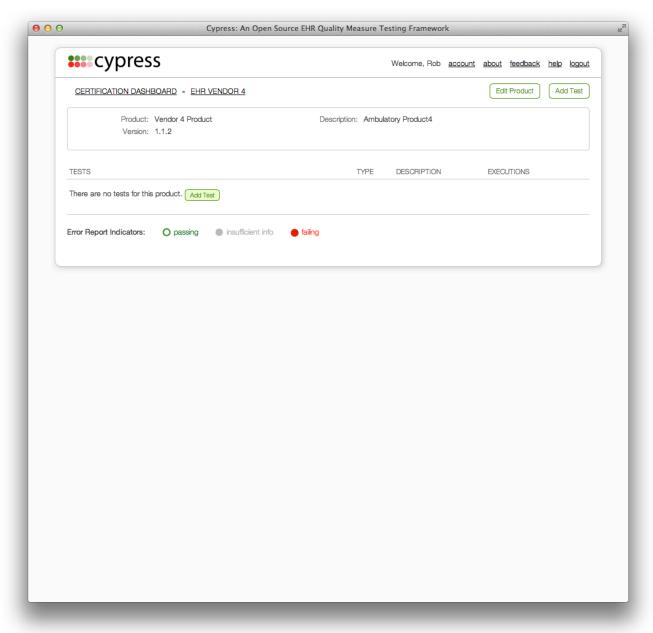






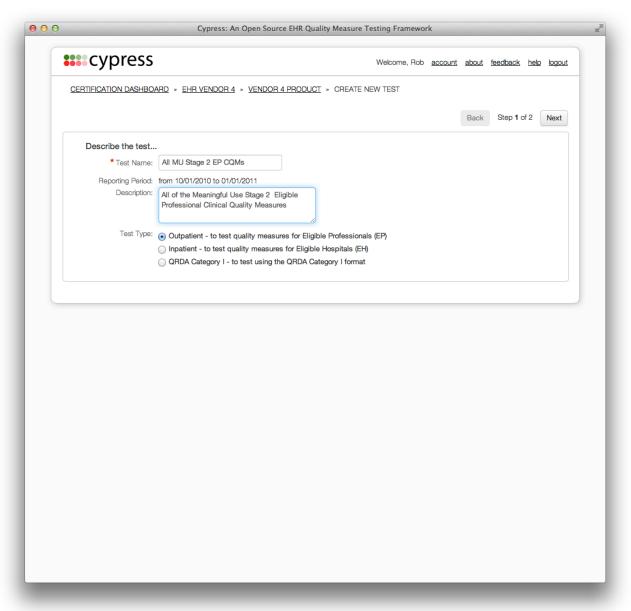






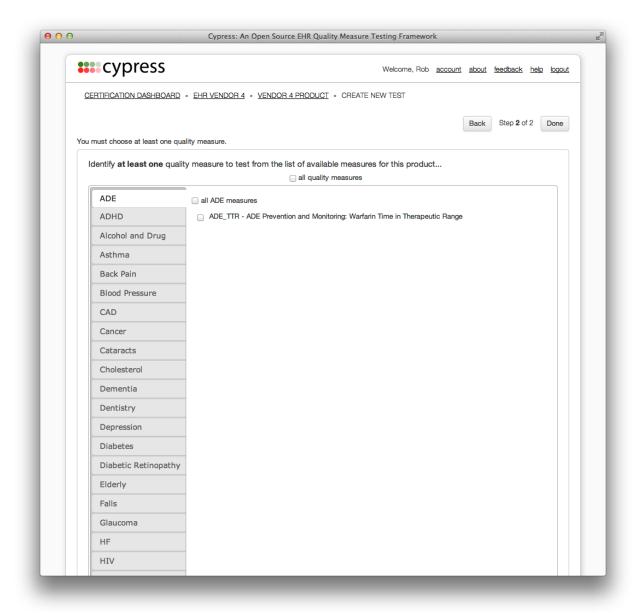






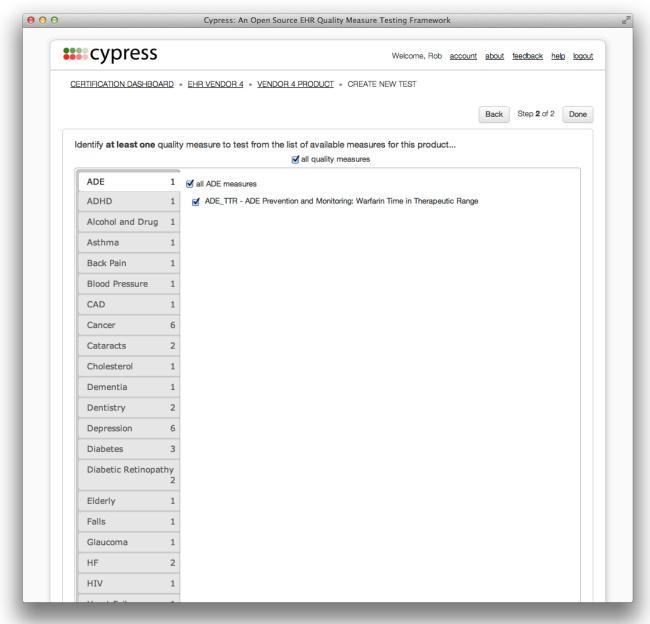






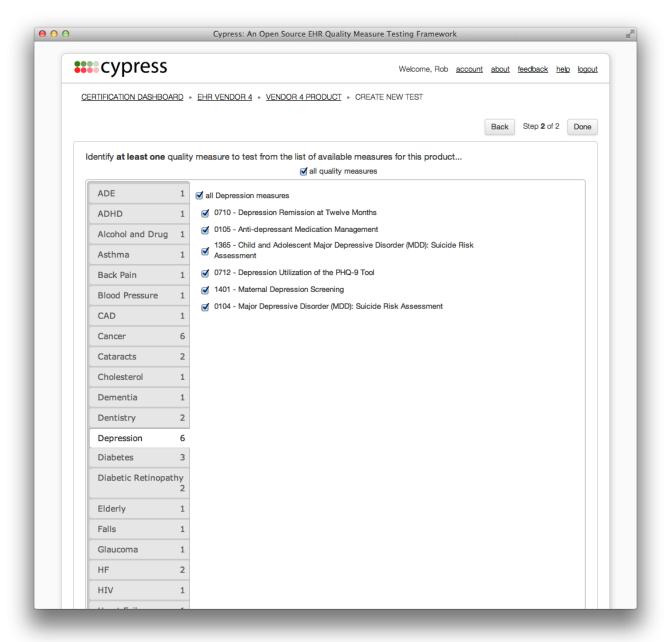






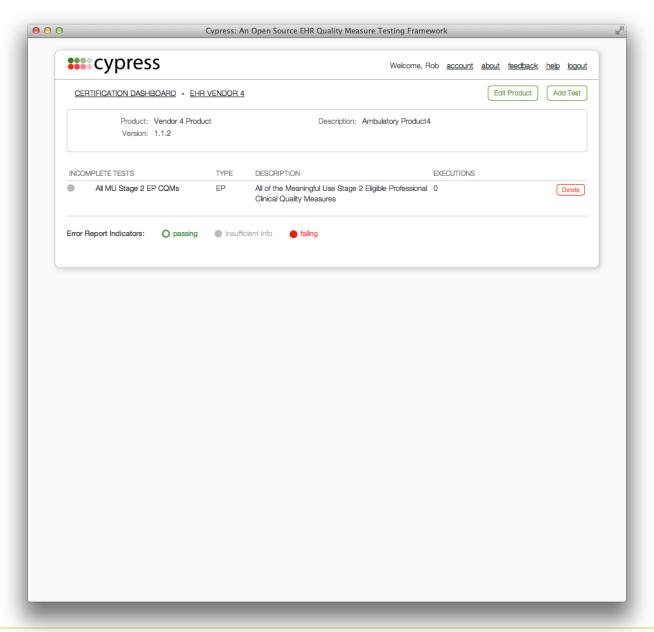




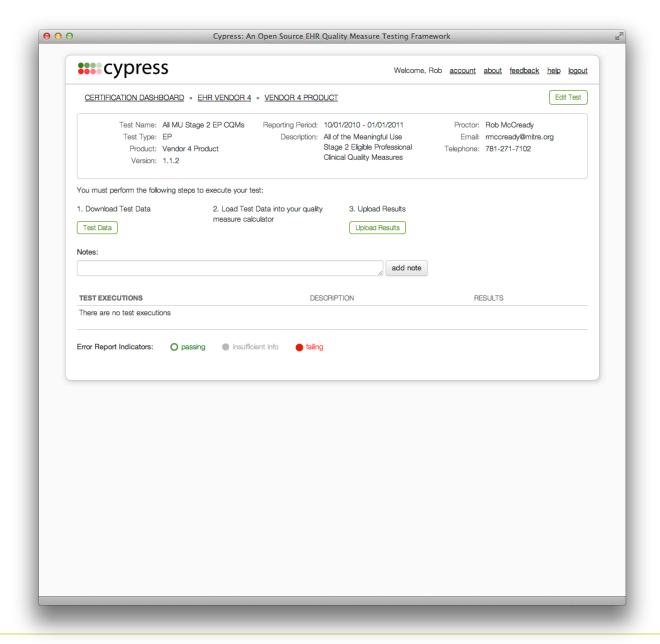






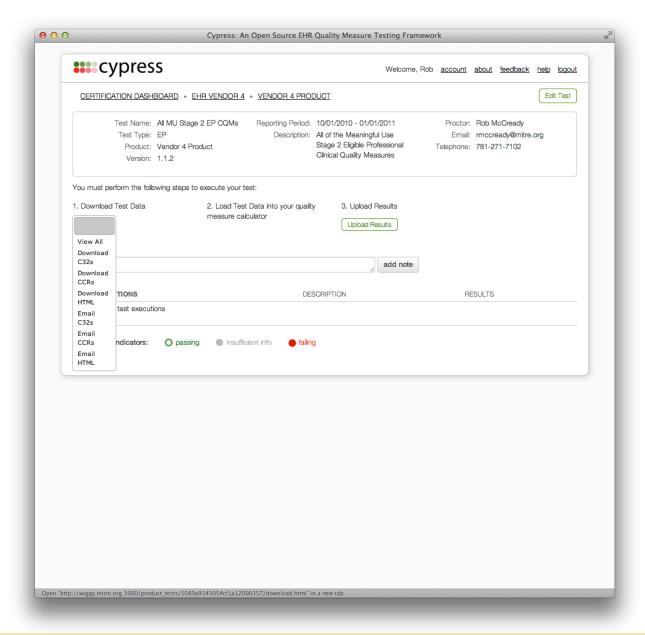
















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